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Proposed Re-evaluation Decision PRVD2015-02

Prosulfuron

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the herbicide prosulfuron, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing prosulfuron for sale and use in Canada.

An evaluation of available scientific information found that products containing prosulfuron do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of prosulfuron uses, new risk-reduction measures are proposed to be included on the labels of all products.

This proposal affects all end-use products containing prosulfuron registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for prosulfuron and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of prosulfuron.

PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Reevaluation*, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Is Prosulfuron?

Prosulfuron is a selective herbicide registered for post-emergent control of broadleaf weeds. It inhibits the plant enzyme acetolactate synthase, also called acetohydroxyacid synthase. It is registered on field corn, seed corn, winter wheat, sorghum and millet. The end-use product is formulated as wettable granules, packaged as water soluble bags, and is applied using ground application equipment only.

Health Considerations

Can Approved Uses of Prosulfuron Affect Human Health?

Prosulfuron is unlikely to affect your health when used according to the label directions.

People could be exposed to prosulfuron by consuming food and water, working as a mixer/loader/applicator, or by entering treated sites. PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Occupational mixer/loader/applicator exposure is not of concern for workers handling prosulfuron according to the current label directions. Further, exposure to workers re-entering treated sites for various activities is not of concern on the day of application. Dietary exposure to prosulfuron through consumption of food commodities and drinking water is not of concern. Currently registered labels include the required mitigation measures and labelling. No additional mitigation measures are proposed pertaining to human health exposure to prosulfuron.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that is at or below the established MRL does not pose an unacceptable health risk.

MRLs for prosulfuron have been established for registered commodities.

Environmental Considerations

What Happens When Prosulfuron Is Introduced Into the Environment?

Prosulfuron is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target terrestrial and aquatic organisms could be exposed to prosulfuron in the environment. Based on exposure and risk assessment conducted by PMRA, the uses of prosulfuron according to the current label are not expected to present a hazard to earthworms, bees, birds and mammals. There is a potential concern for terrestrial and aquatic plants. Buffer zones were updated during re-evaluation using current models, and additional environmental hazard statements are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of prosulfuron, PMRA is proposing further risk-reduction measures related to the environment. No additional risk mitigation measures are proposed related to human health.

Environment

- Environmental hazards statement
- Buffer zone statements to protect non-target, sensitive habitats

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

What Additional Scientific Information Is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on prosulfuron, PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on prosulfuron. PMRA will then publish a Re-evaluation Decision[2] that includes the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to those comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Prosulfuron is a selective systemic herbicide registered for post-emergent control of broadleaf weeds.

Following the re-evaluation announcement for prosulfuron, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the label of commercial class end-use product in Canada.

Currently registered products containing prosulfuron are listed in Appendix I.

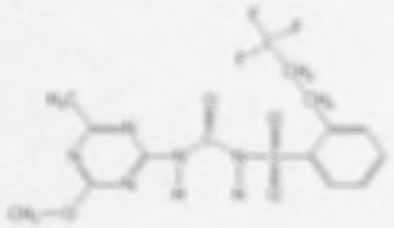
2.0 Use Description of Prosulfuron

Prosulfuron is used on field corn, seed corn, winter wheat, sorghum and millet (USC 13 and 14).

3.0 The Technical Grade Active Ingredient and Its Properties

3.1 Identity of the Technical Grade Active Ingredient

Common name		Prosulfuron
Function		Herbicide
Chemical Family		Sulfonylurea
Chemical Name		
	1 International Union of Pure and Applied Chemistry (IUPAC)	1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)phenylsulfonyl]urea
	2 Chemical Abstracts Service (CAS)	*N*-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]-2-(3,3,3-trifluoropropyl)benzenesulfonamide
CAS Registry Number		94125-34-5
Molecular Formula		$C_{17}H_{19}F_3N_6O_5S$

Structural Formula	
Molecular Weight	419.38
Purity of the Technical Grade Active Ingredient	97.0%
Registration Number	25309

Based on the manufacturing process used, impurities of human health or environmental concerns as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy Track 1 (TSMP Track 1) substances, are not expected to be present in the product.

3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	$< 3.5 \times 10^{-5}$ mPa[1] (2.6×10^{-6} mmHg[2])
UV[3]/visible spectrum	λ_{max} = 227.5 nm (in methanol)
Solubility in water at 25°C	**pH** **mg/L** 4.5 29 5.0 87 6.8 4000 7.7 43000
n-Octanol/water partition coefficient at 25°C	**pH** **log K_{ow}** 5.0 1.5 6.9 -0.21 9.0 -0.76
Dissociation constant	3.76

1. Millipascals
2. Millimetre(s) mercury
3. Ultraviolet

4.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans, and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to prosulfuron may occur through consuming food and drinking water, working as a mixer/loader/applicator, or by entering treated sites.

When assessing health risks, PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

4.1 Toxicology Summary

Metabolism studies in rats demonstrated that prosulfuron was rapidly absorbed, metabolized and excreted after oral or intravenous dosing. Tissue residues were low, often at the limits of detection, indicating a low propensity for accumulation.

Prosulfuron had moderate acute oral toxicity in rats, slight oral toxicity in mice, low dermal toxicity in rabbits and low inhalation toxicity in rats. It was minimally irritating to the rabbit eye and non-irritating to the rabbit skin, and was not a dermal sensitizer in guinea pigs. In a 21-day rabbit dermal study, there were no treatment-related effects.

Transient neurotoxicity affecting primary sensorimotor and gait functions were observed in an acute neurotoxicity study (gavage) in rats. The observations, however, occurred at a dose level equivalent to half the oral LD_{50} in that acute study, and thus with excessive systemic toxicity. In addition any observed neural lesions in the database showed no clear dose response. A 90-day neurotoxicity dietary study did not indicate any treatment-related neurotoxicity.

In oral studies, decreased body-weight gains and/or food consumption were observed. In dogs, the hematopoietic system, liver and heart were identified as target organs. The liver and heart were the primary target organs in rats and mice, respectively. Additional slight effects on hematological and clinical parameters were also noted in these species. A standard battery of genotoxicity/mutagenicity tests (point mutation, unscheduled DNA synthesis, chromosomal aberration and sister chromatid exchange) were carried out. Prosulfuron demonstrated no significant mutagenic and/or genotoxic potential in these tests. No treatment-related neoplastic effects were observed in either the chronic rat or mouse studies.

In a two-generation reproduction rat study, prosulfuron did not have any effects on the production or the delivery of offspring. There were no treatment-related effects on the number of viable pups, pup survival or the incidence of pup macroscopic findings. Reduced litter size, however, was observed at the high dose. In a rabbit developmental study, malformations,

post-implantation loss and abortions were observed, but only in the presence of severe maternal toxicity.

6.3 *Pest Control Products Act* Hazard Considerations

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This takes into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

The toxicity database was complete and was considered adequate for the assessment of risk to infants and children. Data available included a two-generation reproductive toxicity study in rats, and developmental toxicity studies, one in rats, and two in rabbits.

With respect to potential pre- and post-natal toxicity, there was no indication of increased susceptibility in the offspring compared to parental animals. Offspring toxicity (decreased pup body weights and body weight gain) occurred at a maternally toxic dose (decreased body weights) in the reproductive study in rats. No adverse effects were observed on reproduction, and there was no evidence of sensitivity of the young.

In a developmental toxicity study in rats, increased incidences of skeletal variations in pups were noted at a dose that also caused parental toxicity (decreased body weight gains). In one developmental study in rabbits, increased post-implantation loss, abortions and malformations (cranial and cardiovascular) were noted in the presence of severe maternal toxicity at the high dose.

The end points selected for risk assessment were based on no observed adverse effect levels (NOAELs) well below those for reproductive and developmental toxicity and were, therefore, considered protective of these effects. Therefore, for this assessment, the *Pest Control Products Act* factor was reduced from 10-fold to 1-fold.

6.5 Toxicological Endpoints

Appendix B provides an overview of prosulfuron toxicology endpoints used in human health risk assessments by PMRA.

6.6 Dermal Absorption

Since a 90-day oral dog study was used to determine the toxicological endpoints, a dermal absorption factor would be required for route-to-route extrapolation of dermal exposure. Since data is not available to establish a dermal absorption factor for prosulfuron, a 100% default dermal absorption factor was assumed in the re-evaluation review assessments.

6.2 Occupational Exposure

Occupational risk is estimated by comparing potential exposure with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to prosulfuron through mixing, loading and by application using various types of spray equipment or when entering a treated site to conduct activities such as scouting and/or handling treated crops.

6.2.1 Mixer/Loader/Applicator Exposure and Risk

Prosulfuron is registered for field crops including field corn, seed corn, winter wheat, sorghum and millet. Exposure to prosulfuron is expected to be via dermal and inhalation routes for chemical handlers. Exposure duration is expected to be short-term for chemical handlers since the product is applied only once per year. The mixer/loader/applicator assessment was based on workers wearing baseline personal protective equipment, including a single layer with gloves for mixer/loaders, and no gloves for applicators.

The potential occupational exposure was estimated based on exposure data generated by the Pesticide Handlers Exposure Database (PHED), version 1.1.

The short-term risk estimates were generated using a NOAEL of 5.3 mg/kg bw/day from the 90-day oral dog study. The calculated combined dermal and inhalation MOEs were above the target MOE of 100, indicating there is no risk of concern. No additional mitigation measures are proposed.

6.2.2 Postapplication Exposure and Risk

Post-application occupational risk assessments consider dermal exposure to workers entering treated sites to conduct agronomic activities. Given the application timing at very early post-emergent crop stages, post-application activities at early growth stages were considered. Post-application dermal exposure duration is expected to be short- to intermediate-term exposure. Considering low volatility of this active ingredient relative to the North American Free Trade Agreement (NAFTA) criteria for a waiver of inhalation exposure data for outdoor uses (NAFTA, 1999) and assuming at least 12 hours have passed before re-entry, inhalation exposure to prosulfuron is not expected for post-application workers re-entering treated sites.

Potential exposure to post-application workers is estimated using agricultural transfer coefficients and dislodgeable foliar residue. A peak (day 0) dislodgeable foliar residue value of 25% of the application rate was used in the assessment.

The MOE calculated for post-application re-entry workers (all activities) was above the target MOE of 100 and indicated there is no risk of concern. Therefore, no additional mitigation measures are proposed.

4.5.3 Bystander Exposure

Bystander exposure is negligible since the potential for drift is expected to be minimal.

4.5.4 Overall Conclusion for Occupational Exposure and Risk

All registered occupational exposure scenarios were assessed and risks are not of concern. No additional mitigation measures are proposed for mixer/loader/applicant and post-application exposure.

4.6 Non-occupational Exposure

4.6.1 Dietary Exposure and Risk

In a dietary exposure assessment, PMRA determines how much pesticide residue, including residues in milk and meat, may be ingested with the daily diet (food and drinking water). Exposure to prosulfuron from potentially treated imports is also included in the assessment. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The metabolism of prosulfuron in plants and livestock (ruminants and poultry) is adequately understood, and metabolism in the rat follows similar routes as that of livestock.

The residue definition of prosulfuron in Canada under the *Pest Control Products Act*, in plant and animal commodities, is the parent, prosulfuron, only.

4.6.1.1 Acute Dietary Risk

Acute dietary exposure was calculated considering the highest ingestion of prosulfuron that would be likely on any one day, based on high-end estimates of food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of prosulfuron that might be consumed in a day.

The basic acute dietary exposure from food only, for all supported prosulfuron registered and relevant imported commodities, was estimated to be < 2% of the acute reference dose for all the subpopulations.

4.6.1.2 Chronic Dietary Risk

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the acceptable daily intake. This is the dose to which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake of residues is less than the acceptable daily intake, chronic dietary exposure is not of concern.

Established MRLs and/or United States tolerances were used. The basic chronic dietary exposure from all supported prosulfuron food uses for the representative population subgroups was < 1.5% of acceptable daily intake for all the subpopulations.

4.6.2 Residential Exposure and Risk

Prosulfuron is not registered for residential uses. Therefore, a residential exposure risk assessment is not required.

4.7 Aggregate Exposure and Risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Since there is no residential use, aggregate exposure in this re-evaluation combines the different routes of exposure to prosulfuron (in other words, from food and water only). Aggregate acute dietary exposure from food and drinking water is considered acceptable and is below the level of concern, < 10% of the acute reference dose for all the subpopulations. Aggregate chronic dietary exposure from food and drinking water was considered acceptable and below the level of concern, < 2.0% of the acceptable daily intake for all population subgroups.

4.8 Cumulative Exposure and Risk

PMRA has not determined whether prosulfuron has a common mechanism of toxicity with other compounds; therefore a cumulative assessment was not conducted during the re-evaluation.

4.9 Overall Conclusion for Health Risk Assessment

Health risk assessments concluded that health risks are not of concern when the current label directions are followed.

5.0 Environment

5.1 Environmental Fate

Prosulfuron is soluble in water under acidic conditions and very soluble under neutral and alkaline conditions. Based on its vapour pressure, prosulfuron is non-volatile under field conditions. The Henry's law constant indicates that it is not expected to volatilize from moist soils or water surfaces. Based on prosulfuron's dissociation constant, prosulfuron is weakly acidic and exists mainly as an anion at environmentally relevant pHs. Hydrolysis of prosulfuron is pH dependent; prosulfuron was resistant to hydrolysis at neutral and alkaline pH conditions, but rapidly hydrolyzes under acidic conditions. Phototransformation is not expected to be an important route of transformation on soil or in water.

In the terrestrial environment, prosulfuron is expected to be moderately persistent to persistent in aerobic and anaerobic soils.

Prosulfuron demonstrates a high potential for mobility in soil. The combination of low soil adsorption, solubility in water and presence in anionic form under environmentally relevant pH conditions suggest that prosulfuron has the potential to leach through soil into groundwater. The major transformation products, CGA159902 and CGA300406 were also found to have a high to very high potential for mobility in soil. Soil column leaching experiments confirm that prosulfuron is capable of leaching through soil.

In field dissipation and accumulation studies, prosulfuron was found to be non-persistent to slightly persistent. Residues of the major transformation products, CGA159902 and CGA300406, were found to be more persistent than the parent compound under field conditions. Prosulfuron or the transformation products residues were not found below the 0-15 cm depth, indicating limited mobility under field conditions.

In aquatic environments, prosulfuron is expected to be moderately persistent under aerobic conditions and slightly persistent under anaerobic conditions. Persistence in both soil and water is shown to increase with decreasing temperature. In an aquatic field dissipation study, prosulfuron was found to be slightly persistent under aquatic field conditions. The majority of prosulfuron residues are shown to partition into the water phase.

Water monitoring data indicated that prosulfuron was detected in < 3% of surface water samples from three provinces in Canada. The highest concentration of prosulfuron detected was in Ontario (0.0063µg/L). Data from the United States indicated no detection in groundwater. Detection in surface water in the United States was similar to that in surface water in Canada, with a frequency of detection of about 3% with the highest concentration being 0.036 µg/L.

The octanol/water partition coefficient indicates that prosulfuron has a low potential for bioaccumulation.

5.2 Environmental Exposure and Risk Assessment

To assess the ecological risk of prosulfuron to both terrestrial and aquatic non-target plants and animals, expected environmental concentrations were generated based on calculations using worst-case scenarios.

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects of a pesticide on non-target species. The screening-level risk assessment for prosulfuron is based on direct application at the registered application rate.

The calculated risk quotients (RQs) are based on appropriate toxicity end-points, and the expected environmental concentrations and the resulting RQs are compared to the level of concern (LOC = 1). RQs were below 1 for bees, earthworms, birds, mammals and most aquatic species. However, RQs were greater than 1 for terrestrial and aquatic vascular plants. The refined RQ for terrestrial plants is > 2, which remains greater than the level of concern.

5.3 Buffer Zones

Buffer zones were calculated to protect sensitive plant species. Based on the identified risks to non-target species, a two-metre terrestrial buffer zone and a one-metre aquatic buffer zone are required to protect terrestrial and aquatic plants respectively. However, the registered end-use product (Peak 75 WG Herbicide) must be used in a tank mix with other herbicide products. The applicator must consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone and coarsest spray (American Society of Agricultural Engineers) category indicated for the products involved in the tank mixture.

5.4 Overall Conclusion for Environmental Risk Assessment

The environmental risk assessment indicates there are risk concerns for both terrestrial and aquatic plants. Buffer zones are proposed to mitigate the environmental risks. Label statements are proposed based on current labelling practices (Appendix IV).

6.0 Value

Prosulfuron is mainly used in field corn. It has a highly flexible application window (for example, from the 2-leaf stage right through to the 7-leaf stage of corn or up to the beginning of stem elongation of winter wheat). This allows growers to remove weeds at the early stage to prevent competition and help the crop establish quickly. It also provides an option for growers to manage late emerging weeds, or to use prosulfuron as a followup to early post-emergent or pre-emergent treatment.

Prosulfuron is an effective partner herbicide. For broadleaf weed control, prosulfuron must be used only in a tank mix with dicamba or bromoxynil. This tank mix reduces the rate of dicamba or bromoxynil to approximately one half of the normal use rates. The resulting tank mix provides superior crop safety and control of a broad spectrum of broadleaf weeds. This tank mix can also be further partnered with herbicides targeting grass weeds to provide one-pass control of broadleaf weeds and annual grass weeds.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, in other words, persistent in air, soil, water and/or sediment, bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*).

Prosulfuron was assessed in accordance with the PMRA Regulatory Directive DIR99-03, the PMRA strategy for implementing the TSMP. It was concluded that prosulfuron does not meet TSMP Track-1 criteria.

7.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of prosulfuron, contaminants in the technical grade active ingredient (TGAI) were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*[3]. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). PMRA has reached the following conclusion:

- Technical grade prosulfuron does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

8.0 Incident Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to PMRA within a set time frame.

As of 18 March 2014, there were no incident reports in the PMRA database.

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[3] *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

The Ecological Incident Information System (EIIS) of the United States Environmental Protection Agency was queried for environmental prosulfuron incidents that were available in the database as of 18 March 2014. There were 78 incidents reports available in the EIIS database. Incidents in the EIIS database involved various plant species with crop injuries; two incidents caused mortality of plants, the remaining incidents caused plant damage.

9.0 Organisation for Economic Co-operation and Development Status of Prosulfuron

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum where governments can work together to share experiences and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

As of 7 November 2014, prosulfuron is acceptable for use in other OECD countries, including the United States, Australia and European Union Member States. No decision by an OECD member country to prohibit all uses of prosulfuron for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

PMRA has determined that products containing prosulfuron for sale and use in Canada are acceptable for continued registration with the implementation of the proposed label amendments (Appendix IV).

11.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, and DACO tables (data code tables) can be found on the Pesticides and Pest Management portion of the Health Canada website. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through the Environment Canada website.

List of Abbreviations

a.i.	active ingredient
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
bw	body weight
CAS	Chemical Abstracts Service
EIIS	Ecological Incident Information System
g	gram(s)
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
LOC	level of concern
MATC	maximum acceptable toxicant concentration
mmHg	millilitre(s) mercury
MOE	margin of exposure
mPa	millipascal(s)
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PHED	Pesticide Handlers Exposure Database
pH	-log10 hydrogen ion concentration
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RQ	risk quotient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UV	ultraviolet
µg	microgram(s)

Appendix I Registered Prosulfuron Products as of 7 November 2014

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
25309	Technical	Syngenta Canada Inc.	Prosulfuron Technical	Dust	97
25310	Commercial	Syngenta Canada Inc.	Peak 75WG Herbicide	Wettable granule	75

Appendix II Human Health Toxicity Endpoints for Prosulfuron

Exposure Scenario	Dose	Study	Target MOE/ Safety Factor
Acute Dietary	NOAEL = 10 mg/kg bw/day	Acute neurotoxicity study	100
	ARfD = 0.1 mg/kg bw/day		
Chronic Dietary	NOAEL = 5.3 mg/kg bw/day	90-day oral dog study	100
	ADI = 0.053 mg/kg bw/day		
Dermal (short- and intermediate-term)[1]	NOAEL = 5.3 mg/kg bw/day	90-day oral dog study	100
Inhalation (short- and intermediate-term)	NOAEL = 5.3 mg/kg bw/day	90-day oral dog study	100
Cancer	No carcinogenic potential		

[1] Risk assessments assumed 100% dermal and inhalation absorption.

Appendix III Environment

Toxicity of Non-target Species

Organism	Exposure Type	Toxicity
Terrestrial Invertebrates		
Honeybee (*Apis mellifera*)	Acute contact	48-h LD_{50} > 100.9 µg a.i./bee (133.6 kg a.i./ha[1])
	Acute oral	48-h LD_{50} > 100.9 µg a.i./bee (133.6 kg a.i./ha)
Honeybee (*Apis mellifera*)	Acute contact	LD_{50} > 100 µg a.i./bee (132.5 kg a.i./ha)
Earthworm (*Eisenia fetida*)	Acute	14-d LC_{50} > 1000 mg a.i./kg soil
Earthworm (*Eisenia fetida*)	Acute	14-d LC_{50} > 100 mg a.i./kg soil
Birds		
Bobwhite quail (*Colinus virginianus*)	Acute oral	21-d LD_{50} > 2150 mg/kg bw
Mallard duck (*Anas platyrhynchos*)	Acute oral	21-d LD_{50} > 1500 mg/kg bw
Mallard duck (*Anas platyrhynchos*)	Acute oral	14-day LD_{50} >1994 mg a.i./kg bw NOEL = 237 mg/kg bw
Bobwhite quail (*Colinus virginianus*)	Acute dietary	8-d LC_{50} > 5000 mg a.i./kg diet NOEC = 5000 mg a.i./kg diet
Mallard duckling (*Anas platyrhynchos*)	Acute dietary	8-d LC_{50} > 5000 mg a.i./kg diet NOEC = 5000 mg a.i./kg diet
Bobwhite quail (*Colinus virginianus*)	Reproduction	NOEC = 150 mg/kg diet
Mallard duck (*Anas platyrhynchos*)	Reproduction	NOEL = 30 mg/kg diet
Plants		
Vascular plant	Seed germination (Tier I, ryegrass)	NOEC = 0.0228 a.i./a (>128.09 g a.i./ha)
	Seedling emergence (Tier II, ryegrass)	NOEC ≥ 0.17 g a.i./ha
	Vegetative vigour (Tier II, cotton, dicotyledonous species)	NOEC ≥ 0.17 g a.i./ha

[1] Converted (x 1.12) based on Tomlin et al. (1997).

Ingredient	Substance Type	Quantity
Aqueous Ointment		
White flax (*Linum usitatissimum*)	None	400 ft (122 m)
	Cheese	500 oz (140 mg a.i.) fl.
Wood shrimp (*Lithodes hallux*)	None	90 ft (27 m)
Eastern oyster (*Crassostrea virginica*)	None	90 ft (27 m)
Rainbow trout (*Oncorhynchus mykiss*)	None	90 ft (27 m)
Rainbow trout (*Oncorhynchus mykiss*)	None	90 ft (27 m)
Bluegill (*Lepomis macrochirus*)	None	90 ft (27 m)
Bluegill (*Lepomis macrochirus*)	None	90 ft (27 m)
Common carp (*Cyprinus carpio*)	None	90 ft (27 m)
Catfish (*Ictalurus punctatus*)	None	90 ft (27 m)
Shorthead redhorse (*Moxostoma macrolepidotum*)	None	90 ft (27 m)
Rainbow trout (*Oncorhynchus mykiss*)	Cheese	25 ft (7.6 m)
Fathead minnow (*Pimephales promelas*)	Early life-stage toxicity	500 ft (150 m)
Dogwood (*Cornus spp.*)	—	100 ft (30 m)
Freshwater Bivalve (*Unionida publications*)	—	5 ft (1.5 m)
Freshwater green alga (*Selenastrum capricornutum*)	—	5 ft (1.5 m)

Organism	Exposure Type	Toxicity
Freshwater filamentous blue-green alga (*Anabaena flos-aquae*)	—	5-d EC_{50} > 27.2 µg a.i./L
Marine diatom (*Skeletonema costatum*)	—	5-d EC_{50} > 28.6 µg a.i./L

Appendix IV Label Amendments for Products Containing Prosulfuron

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

For the technical grade active ingredient product:

1. Add a section entitled "**ENVIRONMENTAL HAZARDS**".

   TOXIC to aquatic organisms.

2. In the section entitled **PRECAUTIONS**, add the following:

   DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

For end use product,

1. Add a section entitled **"ENVIRONMENTAL HAZARDS"**.

   TOXIC to aquatic and non-target terrestrial plants. Observe buffer zones specified under "DIRECTIONS FOR USE".

   The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or the depth to the water table is shallow.

   To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

   Avoid application when heavy rain is forecast.

   Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

2. In the section entitled **DIRECTIONS FOR USE**, add the following:

   As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

   DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer Zones

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

As PEAK 75 WG Herbicide must be used in a tank mix with other herbicide products, the applicator must consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) DFR category indicated on the labels for those tank mix partners.

3. Delete the third point and the buffer zones table under the **USE PRECAUTIONS** section.

References

Studies Considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1462390	1992, Technical Chemistry file – CGA 152005 Prosulfuron: Report on General Physico-Chemical Properties, DACO: 2.14.1, 2.14.2, 2.14.3
1462383	1992, Technical Chemistry file – CGA 152005 Prosulfuron – Report on Melting Point/Melting Range, DACO: 2.14.4
1462387	1992, Technical Chemistry file – CGA 152005 – Report on Vapour Pressure Curve, DACO: 2.14.9
1462388	1992, Technical Chemistry file – CGA 152005 – Report on Density of Solids, DACO: 2.14.6
1462384	1992, Technical Chemistry file – CGA 152005 – Report on Water Solubility, DACO: 2.14.7
1462391	1992, Technical Chemistry file – CGA 152005 – Prosulfuron: Report on Solubility in Organic Solvents, DACO: 2.14.8
1462386	1992, Technical Chemistry file – CGA 152005 – Report on Dissociation Constant in Water, DACO: 2.14.10
1462385	1992, Technical Chemistry file – CGA 152005 – Report on Octanol/Water Partition Coefficient, DACO: 2.14.11
1461792	1994, Report on Spectra CGA 152005, DACO: 2.14.12
1461782	1994, Chemical Stability of CGA 152005 – http://blog.ca/register/register. Technical at Ambient Temperature, DACO: 2.14.13
1462372	Technical Chemistry file – Manufacturing Process CGA 152005, DACO: 2.11.3, 2.11.4
1462400	1992, Technical Chemistry file – CGA 152005 – Prosulfuron: Storage Stability for Active Ingredient, DACO: 2.14.14 CBI

Studies Considered in the Health Risk Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1148403	Acute oral toxicity study of CGA 152005 technical in rats (HWI10302700) (prosulfuron). DACO 4.2.1
1148384	Final report – Acute oral toxicity study of CGA 152005 technical in mice (HWI10302701) (prosulfuron). DACO 4.2.1
1148385	Final report – Acute dermal toxicity study of CGA 152005 technical in rabbits (HWI10302702) (prosulfuron). DACO 4.2.2
1148386	CGA 152005 tech. Acute inhalation toxicity in the rat (911203) (prosulfuron). DACO 4.2.3
1148387	Final report – Primary eye irritation study of CGA 152005 technical in rabbits (HWI10302704) (prosulfuron). DACO 4.2.4
1148388	Final report – Primary dermal irritation study of CGA 152005 technical in rabbits (HWI10302703) (prosulfuron). DACO 4.2.5
1148389	Final report – Dermal sensitization study of CGA 152005 technical in guinea pigs – closed patch technique (HWI10302705) (prosulfuron). DACO 4.2.6
1168420	Skin sensitisation test in the guinea pig maximisation test (921058) (prosulfuron technical herbicide). DACO 4.2.6
1164218	4-week dietary rangefinder toxicity study with CGA 152005 in mice (F-00056) (Peak 75WG/prosulfuron herbicide). DACO 4.7
1164219	90-day dietary toxicity study with CGA 152005 in mice final report (f-00058) (Peak 75WG/prosulfuron herbicide). DACO 4.7
1148390	CGA 152005 technical 28-days oral cumulative toxicity study in rats (gavage) final report (921043) (prosulfuron). DACO 4.3.1
1148391	CGA 152005 technical 21-day dermal toxicity study in rabbits (911233) (prosulfuron). DACO 4.3.1
1148392	90-day dietary toxicity study with CGA 152005 technical in beagle dogs – Final report (F-00062;409;82-1)(prosulfuron). DACO 4.3.1

1148393 CGA 152005 technical 21-day dermal toxicity study in rabbits (911233) (prosulfuron). DACO 4.3.4

1148412 1-year dietary toxicity study with CGA-152005 technical in beagle dogs – Final report (f-00063) (prosulfuron). DACO 4.4.1

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1148405 18-month dietary oncogenicity study with CGA 152005 technical in mice (F-00060;83-2;451) (prosulfuron), part 1. DACO 4.4.2

1148406 18-month dietary oncogenicity study with CGA 152005 technical in mice (F-00060;83-2;451) (prosulfuron), part 2. DACO 4.4.2

1148404 Two-year dietary chronic toxicity/oncogenicity study with CGA 152005 technical in rats (f-00059;453;83-5) (prosulfuron). DACO 4.4.1, 4.4.2

1149285 Amendment number 1 to final report 18-month dietary oncogenicity study with CGA-152005 technical in mice (f-00060) supplement to EPA MRID No. 43159316 (prosulfuron). DACO 4.4.1, 4.4.2

1168424 1-year dietary toxicity study with CGA 152005 technical in beagle dogs – Method of urine collection & grading system for histopathological lesions (SOP: V-07-010.001;F-00063) (prosulfuron technical herbicide). DACO 4.4.5

1148413 A two-generation reproduction study in rats with CGA 152005 technical final report (f-00082;416;4200;540/9-82-025) (prosulfuron). DACO 4.5.1

1149287 Amendment 2 to final report a two-generation reproduction study in rats with CGA-152005 technical (f-00082) supplement to EPA MRID No. 43159319 (prosulfuron). DACO 4.5.2

1164220 A rangefinding teratology probe in cd rats with CGA 152005 technical final report (F-00074;42700001) 9Peak 75WG/prosulfuron herbicide). DACO 4.5.2

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1164221 A range finding teratology probe in rabbits with CGA 152005 technical (F-00076;42685238) final report (Peak 75WG/prosulfuron herbicide). DACO 4.5.2

1166915 A teratology range finding probe in rabbits with CGA 152005 technical. A final report completed on March 29, 1995. (F-00194). (prosulfuron technical). DACO 4.5.2

1166917 Dose range-finding developmental toxicity study in rabbits with CGA 152005 technical. A final report completed on January 29, 1996. (CHV2386-107) (prosulfuron technical). DACO 4.5.2

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1166918 CGA 152005 technical – Dose range-finding developmental toxicity study in rabbits. Amendment to final report completed on January 29, 1996. (CHV2386-107). (prosulfuron technical). DACO 4.5.2

1166919 CGA 152005 technical – A teratology study in rabbits with CGA-152005 technical. A final report completed on 1/26/96.(F00195). (prosulfuron technical). DACO 4.5.2

1166916 A teratology study in rabbits with CGA 152005 technical. A final report completed on 12/15/94.(f-00188).(prosulfuron technical). DACO 4.5.2

1148419 CGA-152005 technical gene mutations test *Salmonella* and *Escherichia*/liver-microsome test (911231) (prosulfuron). DACO 4.5.4

1148407 CGA-152005 technical gene mutations test cytogenetic test on Chinese hamster cells *in vitro* (901472) (prosulfuron). DACO 4.5.4

1148408 CGA-152005 technical gene mutations test with Chinese hamster cells V79 (OECD CONFORM) *in vitro* (901473) (prosulfuron). DACO 4.5.4

1148409 CGA-152005 technical structural chromosomal aberration test micronucleus test, mouse (901469) (prosulfuron). DACO 4.5.4

1148410 CGA-152005 technical tests for other genotoxic effects autoradiographic DNA repair test on rat hepatocytes (901470) (prosulfuron). DACO 4.5.4

1164222 Final report – Acute rangefinding neurotoxicity study with CGA 152005 in rats (f-00131) (Peak 75WG/prosulfuron herbicide). DACO 4.5.10

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1132214	Metabolism: Note to Reviewer. DOCA 6.1
1132215	Response to EPA Review of Prosulfuron: Nature of the Residue in Corn and Ruminants. DACO 6.3
1148421	Analytical phase I (mass balance) report for the metabolism of phenyl-14C-CGA-152005 and triazine-14c-CGA-152005 in field corn grown in Illinois (prosulfuron). DACO 6.3
1148422	Uptake and metabolism of CGA-152005 in field rotational crops following a 1x bareground treatment with phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 (prosulfuron). DACO 6.3
1148423	Stability of CGA-152005 metabolites in greenhouse grown corn after spray treatment with phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 (prosulfuron). DACO 6.3
1148425	Biological report for stability of CGA-152005 metabolites in greenhouse grown corn after spray treatment with phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 (prosulfuron). DACO 6.3
1148450	Uptake and metabolism of CGA-152005 in greenhouse grown corn after spray treatment or stem injection with phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 (prosulfuron). DACO 6.3
1148451	Biological phase report for uptake and metabolism of CGA-152005 in greenhouse grown corn after spray treatment or stem injection with phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 (prosulfuron). DACO 6.3
1148452	Prosulfuron: analytical phase I (mass balance) report for the uptake and metabolism of CGA-152005 in greenhouse grown corn after spray treatment or stem injection with phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 (prosulfuron). DACO 6.3
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1148454	Biological phase report for the uptake and metabolism of phenyl-14C-CGA-152005 and triazine-14C-CGA-152005 in field corn grown in Illinois (prosulfuron). DACO 6.3
1148411	Metabolism of [triazine-4-14c] CGA-152005 in the rat (F-00106,417) (prosulfuron). DACO 6.4
1148420	Metabolism of [triazine-4-14C] CGA-152005 in the rat addendum 1 to the final report (F-00106) (prosulfuron). DACO 6.4

1148426 Metabolism of [triazine-14C] CGA-152005 in the chicken (prosulfuron). DACO 6.4

1148427 Metabolism of [phenyl-14C] CGA-152005 in the chicken (prosulfuron). DACO 6.4

1148432 Metabolism of [phenyl-14C] CGA-152005 in the rat (F-00112) (prosulfuron). DACO 6.4

1148443 Metabolism of [triazine-14C] CGA-152005 in lactating goats after multiple oral administrations (ABR-93041;168989) (prosulfuron). DACO 6.4

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1160873 Absorption and distribution kinetics of [4-14C] triazine CGA 152005 in the rat. (019AM01;pp2.44CH;15/94) (prosulfuron/Peak 75WG). DACO 6.4

1132216 Summary of the Residue Trials Done in Corn with Adjuvant and Dicamba. DACO 7.1

1162399 October 12, 1995, Summary of residue data from Canada and proposal for establishment of PHI's in corn and MRL's in corn and animal products. (Peak 75WG). DACO 7.1

1148428 CGA 152005 determination of residues of parent compound by microbore high performance liquid chromatography (HPLC) (prosulfuron). DACO 7.2.1

1148429 Analytical method for the determination of CGA-152005 in crops by high performance liquid chromatography with column switching including validation data (prosulfuron). DACO 7.2.1

1148430 Analytical method for the determination of CGA-152005 in meat, milk, blood and eggs by high performance liquid chromatography including validation data (prosulfuron). DACO 7.2.1

1148431 Analytical method for the determination of CGA-152005 in canine, rodent, and avian feed by reverse phase liquid chromatography including validation data (168974;144-90;AG-578) (prosulfuron). DACO 7.2.1

1164212 Analytical method for the determination of CGA-152005 in crops by high performance liquid chromatography with column switching including validation data supercedes AG-590 (AG-590A)(peak 75WG/prosulfuron herbicide). DACO 7.2.1

1164224 Specificity of analytical method AG-590 for the determination of CGA-152005 in crops (Peak 75WG/prosulfuron herbicide). DACO7.2.1

1182160 Determination of CGA 136872 in Corn and Corn Fractions by High Performance Liquid Chromatography, W.T. Beidler et al., July 27, 1988 (Ag-499a) [Beacon 75wg Herbicide;Subm #97-0352;Submitted February 17, 1997;Volume 2]. DACO 7.2.1

1132219 Determination Of Dicamba And 5-Hydroxy Dicamba Residues In Barley, Corn, Cotton, Cotton Processed Fractions, Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat And Wheat Processed Fractions (GC). DACO 7.2.1

1148436 Stability of CGA-152005 fortified into corn substrates under freezer storage conditions twelve-month interim report (ABR-93054;168001;144-92) (prosulfuron). DAOC 7.3

1148437 Storage stability of field-incurred residues of CGA 152005 in corn (whole plant) under freezer storage conditions twelve-month interim report (ABR-93038;168986;121-92) (prosulfuron). DACO7.3

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1132220 PEAK 75WG Herbicide – Four Crop Residue Trials to Verify the Absence of Residues of Parent Compounds and Significant Metabolites after Application of BEACON or PEAK in Tank Mixes with Dicamba and Adjuvants on Field Corn. DACO7.4.1

1873006 Prosulfuron (A8714C) – Residue Levels on Winter Wheat (Hay, Grain, and Straw) from Trials Conducted in Canada During 2008. DACO7.4.1

1073009 CGA 152005 – Magnitude of the Residues in/on Wheat and Grain Sorghum, Representative Commodities of the Cereal Grains Crop Group, Following a Post Application. DACO 7.4.1, 7.4.2, 7.4.5

1149288 Residues of CGA152005 in maize (silage and cobs) from field trials in Canada (3146/93;3147/93) (prosulfuron). DACO 7.4.2

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1164213 CGA 152005 – Magnitude of the residues in/on corn, including processed fractions and rotational crops, following a post application (peak 75WG /prosulfuron herbicide). DACO 7.4.2

1168433 CGA 152005 – U.S. residue data on corn forage, fodder and grain (168001, 31-91 parts A&B.02-88R-003-91) (prosulfuron). DACO 7.4.6

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Studies considered in the Environmental Risk Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

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1169266	Kesterson, A. 1992. CGA 152005 – Solution photolysis of Triazine – ^{14}C-CGA 152005 in natural sunlight. Report No. 570. 127 pp. DACO 8.2.1
1169265	Kesterson, A. 1992. CGA 152005 – Solution photolysis of Phenyl – ^{14}C-CGA 152005 in natural sunlight. Report No. 569. 125 pp. DACO 8.2.1
1169263	Kesterson, A. 1993. CGA 152005 – Hydrolysis of [^{14}C]Phenyl CGA 152005 at pH 5, 7 and 9. Report No. 551. 121 pp. DACO 8.2.1

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1140309	Adkins, R.H. 1993c. CGA 152005 – Anaerobic metabolism of Triazine – ^{14}C-CGA 152005 in sandy loam soil. Report No. 586. 103 pp. DACO 8.2.3.1
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1140312	Adkins, R.H. 1994. CGA 152005 – Aerobic metabolism of Triazine – ^{14}C-CGA 152005 in soil at approximately pH 6. Report No. 636. 212 pp. DACO 8.2.3.1
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